

Attachment 16

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

Docket No. FDA-2019-N-3065

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

This proposed rule would require that one of up to 13 new cigarette health warnings, each comprising a textual warning statement paired with an accompanying color graphic, appear on cigarette packages and in cigarette advertisements. The proposed rule would further require that, for cigarette packages, the required cigarette health warnings be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly and equally distributed throughout the United States in accordance with a plan approved by the Food and Drug Administration (FDA). The proposed rule would also require that, for cigarette advertisements, the required cigarette health warnings must be rotated quarterly in alternating sequences in advertisements for each brand of cigarettes in accordance with a plan approved by FDA. The proposed new cigarette health warnings would promote greater public understanding of the negative health consequences of cigarette smoking by presenting information about the health risks of smoking to smokers and nonsmokers in a format that helps people better understand these consequences. Despite the informational effects of this proposed rule, there is a high level of uncertainty around quantitative economic benefits at this time, so we describe them qualitatively. The cost of this proposed rule consists of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of required cigarette health warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule. We estimate that, at the mean, the present value of the costs of this proposed rule is about \$1.6 billion using a three percent discount rate and roughly \$1.2 billion using a seven percent discount rate (2018\$). If the information provided by the cigarette health warning on each cigarette package was valued at about \$0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the proposed rule would equal or exceed the estimated annual costs.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

Summary and Accounting Statement

This proposed rule would require that one of up to 13 new cigarette health warnings,² each comprising a textual warning statement paired with an accompanying color graphic image, appear on cigarette packages and in cigarette advertisements. The proposed rule would further require that, for cigarette packages, the required cigarette health warnings be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed throughout the United States in accordance with a plan approved by the Food and Drug Administration (FDA). The proposed rule would also require that, for cigarette advertisements, the required cigarette health warnings must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan approved by FDA.

² To the extent the number of warnings included in a final rule is less than 13, the costs of the rule would accordingly be less. For purposes of this analysis, we base our estimates on the assumption that 13 warnings would be required.

Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning's message, increase knowledge and learning of the negative health consequences of smoking, and benefit diverse populations that have disparities in knowledge about the negative health consequences of smoking.

The direct economic benefits of providing information on cigarette health warnings are difficult to quantify, and we do not predict the size of these benefits at this time. We discuss the informational effects qualitatively.

The cost of this proposed rule consists of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of required cigarette health warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule. Using a 20-year time horizon, we estimate that the present value of the costs of this proposed rule ranges from \$1.3 billion to \$1.9 billion, with a mean estimate of \$1.6 billion, using a three percent discount rate, and ranges from \$1.0 billion to \$1.5 billion, with a mean estimate of \$1.2 billion, using a seven percent discount rate (2018\$). Annualized costs, which are presented below in Table 1, range from \$88.6 million per year to \$129.7 million per year, with a mean estimate of \$107.5 million per year, using a three percent discount rate, and range from \$94.6 million per year to \$139.8 million per year, with a mean estimate of \$115.3 million per year, using a seven percent discount rate (2018\$).

Because it is not possible to compare benefits and costs directly when the benefits are not quantified, we employ a break-even approach. If the information provided by the cigarette health warning on each cigarette package was valued at about \$0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the proposed rule would equal or exceed the estimated annual costs.

Table 1. Summary of the Informational Effects and Costs of the Proposed Rule (in millions of 2018\$)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Informational Effects		Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning’s message, increase knowledge and learning of the negative health consequences of smoking and help reduce disparities in knowledge about the negative health consequences of smoking across diverse populations. If the information provided by the cigarette health warning on each cigarette package was valued at about \$0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the proposed rule would equal or exceed the estimated annual costs.						
Costs	Annualized Monetized \$millions/year	\$115.3	\$94.6	\$139.8	2018	7%	20 Years	Effective date of 15 months from date of publication of final rule.
		\$107.5	\$88.6	\$129.7	2018	3%	20 Years	

In line with Executive Order 13771, in Table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these costs, this proposed rule would be considered a regulatory action under EO 13771.

costs are associated with activities related to reviewing and updating records of labeling information. Finally, inventory costs comprise discarded inventory and disposal costs for labels or printed packages that become obsolete as a result of the labeling requirement (for effective dates of 24 months or longer from the date of publication of the final rule, the model estimates that there are no discarded inventory and disposal costs). To calculate inventory costs, the model estimates the cost per sales unit of each printed package or label and multiplies this value by the estimated remaining inventory, the latter which varies by distance of effective date from the date of publication of the final rule. To provide a range of costs estimates for the requirements of this proposed rule, and as stated above, we present costs at the low, mean and high levels as estimated by the FDA Labeling Cost Model.

The model estimates that a labeling change requires a minimum of 15 months to fully implement, and that any labeling change that must be incorporated in 15 months or less always incurs overtime and rush charges (equal to 40 percent of labor, materials, and recordkeeping costs) for completing all of the label change activities on a faster than usual schedule and sometimes (for effective dates of nine months or less from the date of publication of the final rule) incurs costs associated with applying stickers to some sales units due to insufficient time to print new labels before the change must be implemented. The model further estimates that manufacturers who can coordinate a required labeling change (regulatory labeling change) with a planned voluntary labeling change (non-regulatory labeling change) would incur lower costs associated with the required labeling change than they would otherwise. Farther out effective dates increase the proportion of required labeling changes that can be coordinated with planned voluntary labeling

Break-even Calculation

This proposed rule would promote greater public understanding about the negative health consequences of smoking through updated cigarette health warnings on cigarette packages and in cigarette advertisements. As described above, consumers would receive the information provided in the cigarette health warnings.

Instead of developing quantitative estimates of economic benefits at this time, which present unique challenges, we undertake a break-even calculation to describe the magnitude of non-quantified benefits required for the benefits to equal or exceed the costs of the regulation.

The mean estimate of the cost of this proposed rule, annualized over 20 years, is \$107.5 million per year using a three percent discount rate and \$115.3 million per year using a seven percent discount rate (2018\$). The welfare gains of this proposed rule would come from the value consumers receive from the information provided in the cigarette health warnings on cigarette packages and advertisements. Both smokers and nonsmokers would be exposed to these cigarette health warnings because cigarette health warnings on advertisements would be seen in public spaces and cigarette packages are not always concealed and are often visible to those other than the person carrying the package [Ref. 11, 51]. However, we do not know what proportion of the public would be exposed to the cigarette health warnings. Thus, we estimate a break-even point on a per cigarette package basis.

Using Nielsen RMS data, we estimated that about 9.7 billion packs of cigarettes were sold in the United States in 2018.¹³ If the information provided by the cigarette

¹³ FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS

health warning on each cigarette package were valued at about \$0.01 (for every pack sold annually nationwide), then the benefits generated by the proposed rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018\$).

This per-pack estimate provides one way to estimate the value the public would need to receive from the information provided on the cigarette health warnings in order to break even with the costs of the rule and is equivalent to 0.16 percent of the average cost of a pack of cigarettes, based on a national average cost of \$6.27 per pack.¹⁴ Note that this break-even calculation does not include the value of information provided to the public through cigarette health warnings on advertisements because we do not know the current number of cigarette advertisements. The break-even point would be even smaller if we included the benefits generated by cigarette health warnings on advertisements.

service for the cigarettes category for the 52-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See <http://www.nielsen.com/us/en.html> for more information. Nielsen RMS data do not capture all cigarette sales. For example, the FTC reports that in “2017, the major cigarette manufacturers sold 229.1 billion cigarettes domestically,” or 11.5 billion packs of 20 cigarettes (see page 2 of the FTC Cigarette Report). Note, however, that use of the FTC sales figure in place of the Nielsen sales figure does not change our annualized cost estimates of the proposed rule, and only very slightly changes our breakeven estimate, from about \$0.012 annually to \$0.010 annually.

¹⁴ FDA’s own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 11-week period ending March 23, 2019 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See <http://www.nielsen.com/us/en.html> for more information.

analysis, and our estimate of the annualized value of total costs in the sensitivity analysis is \$0.9 million larger than in the primary analysis, regardless of the discount rate used (2018\$).

The break-even point in this sensitivity analysis is very similar to the estimate presented in the primary analysis above. If the information provided by the cigarette health warning on each package were valued at about \$0.01 (for every pack sold annually nationwide), then the benefits generated by the proposed rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018\$).

Analysis of Regulatory Alternatives to the Proposed Rule

We consider three regulatory alternatives to the proposed rule: an otherwise identical rule with a proposed effective date of 24 months from the date of publication of the final rule, an otherwise identical rule with a proposed effective date of 6 months from the date of publication of the final rule, and an otherwise identical rule requiring that one of up to nine new cigarette health warnings, each comprising a textual warning statement paired with an accompanying color graphic, appear on cigarette packages and in cigarette advertisements. We estimate costs and do a break-even calculation for these alternatives below, although not all regulatory alternatives may be legally viable.

1. Effective Date of 24 Months from Date of Publication of Final Rule

An effective date of 24 months from the date of publication of the final rule would reduce the one-time costs of this rule through three avenues: the number of UPCs that can be coordinated with a previously scheduled label change is increased, rush charges for the label design are eliminated, and discarded inventory costs are eliminated. Table 10 shows the total cost of a major cigarette labeling change that reflects both an

effective date of 24 months from the date of publication of the final rule, as well as that each cigarette UPC would require 13 printing plates, one for each cigarette health warning label (13 warnings per UPC). Looking at Table 10, we estimate total labeling costs associated with the proposed rule under this regulatory option range from \$217.0 million to \$360.3 million, with a mean estimate of \$281.8 million (2018\$).

Table 10. Cost of a Major Cigarette Label Change With 13 Warning Labels (in 2018\$)

	Low	Mean	High
<u>Label Design Costs</u>			
# Uncoordinated UPCs	2,392	2,392	2,392
Labor Costs (\$/UPC)	\$3,211	\$6,860	\$12,906
Material Costs (\$/UPC)	\$69,380	\$87,752	\$108,610
Recordkeeping Costs (\$/UPC)	\$35	\$67	\$116
Total Costs (\$/UPC)	\$72,626	\$94,679	\$121,632
Total Label Design Costs for Uncoordinated UPCs (\$)	\$173,721,392	\$226,472,168	\$290,943,744
# Coordinated UPCs	671	671	671
Labor Costs (\$/UPC)	\$395	\$1,354	\$3,059
Material Costs (\$/UPC)	\$64,043	\$81,002	\$100,256
Recordkeeping Costs (\$/UPC)	\$17	\$34	\$60
Total Costs (\$/UPC)	\$64,455	\$82,390	\$103,375
Total Label Design Costs for Coordinated UPCs (\$)	\$43,249,305	\$55,283,690	\$69,364,625
TOTAL LABEL DESIGN COSTS (\$)	\$216,970,697	\$281,755,858	\$360,308,369
<u>Inventory Costs</u>			
# Discarded Labels	0	0	0
Cost Per Discarded Label (\$/Label)	\$0.027	\$0.032	\$0.037
TOTAL INVENTORY COSTS (\$)	\$0	\$0	\$0
TOTAL COSTS	\$216,970,697	\$281,755,858	\$360,308,369

Notes: FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 52-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See <http://www.nielsen.com/us/en.html> for more information. Effective date is 24 months from date of publication of final rule. We used 2018 Nielsen RMS data to estimate the number of cigarette UPCs. The number of uncoordinated and coordinated UPCs depend on the number of cigarette UPCs as well as, respectively, the percentage of UPCs which cannot and can be coordinated, both of which are estimated using the FDA Labeling Cost Model. The number of discarded labels depends on the estimated number of sales units, the source of which is 2018 Nielsen RMS data, as well as an estimate of the percentage of those sales units which will be discarded, the latter which is estimated using the FDA Labeling Cost Model. Lastly, note that Nielsen only provides a point estimate of UPCs and sales units, not a range. Hence, the number of UPCs and the number of discarded labels is the same at low, mean, and high.

The total cost of the proposed rule if the effective date is 24 months from the date of publication of the final rule is presented in Table 11. The present value of the estimated total costs of the proposed rule ranges from \$1.3 billion to \$1.8 billion, with a mean estimate of \$1.5 billion, using a three percent discount rate, and ranges from \$916.6 million to \$1.4 billion, with a mean estimate of \$1.1 billion, using a seven percent discount rate (2018\$). The estimated annualized cost of the proposed rule ranges from \$82.6 million to \$119.6 million, with a mean estimate of \$99.6 million, using a three percent discount rate, and ranges from \$86.5 million to \$126.1 million, with a mean estimate of \$104.7 million, using a seven percent discount rate (2018\$).

Table 11. Estimated Total Cost of the Proposed Rule if the Effective Date is 24 Months from the Date of Publication of the Final Rule (in millions of 2018\$)

	Non-Discounted		
t	Low	Mean	High
1	\$241.1	\$306.3	\$385.2
2	\$24.1	\$24.5	\$24.9
3	\$24.1	\$24.5	\$24.9
4	\$206.0	\$257.0	\$316.6
5	\$24.1	\$24.5	\$24.9
6	\$24.1	\$24.5	\$24.9
7	\$191.7	\$238.7	\$293.7
8	\$24.1	\$24.5	\$24.9
9	\$24.1	\$24.5	\$24.9
10	\$178.5	\$221.9	\$272.6
11	\$24.1	\$24.5	\$24.9
12	\$24.1	\$24.5	\$24.9
13	\$166.4	\$206.3	\$253.0
14	\$24.1	\$24.5	\$24.9
15	\$24.1	\$24.5	\$24.9
16	\$155.1	\$192.0	\$235.1
17	\$24.1	\$24.5	\$24.9
18	\$24.1	\$24.5	\$24.9
19	\$144.8	\$178.8	\$218.5
20	\$24.1	\$24.5	\$24.9
Present Value			
3%	\$1,229.4	\$1,481.9	\$1,779.0
7%	\$916.6	\$1,108.9	\$1,335.8
Annualized Amount			
3%	\$82.6	\$99.6	\$119.6
7%	\$86.5	\$104.7	\$126.1

Notes: Effective date is 24 months from date of publication of final rule. Included in $t = 1$ is the initial cost associated with changing cigarette labels, illustrated in Table 4. Included in $t = 4, 7, 10, 13, 16$, and 19 are costs associated with planned future cigarette labeling changes from Table 5. Included in $t = 1$ through $t = 20$ are annual design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements from Table 6, advertising opportunity costs illustrated in Section 4, and government administration and enforcement costs illustrated in Section 5.

If the information provided by the cigarette health warning on each package were valued at about \$0.01 (for every pack sold annually nationwide), then the benefits generated by the proposed rule with an effective date of 24 months from the date of

publication of the final rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018\$).

2. Effective Date of Six Months from Date of Publication of Final Rule

With an effective date of six months from the date of publication of the final rule, the FDA Labeling Cost Model estimates that there is not enough time for any of the labeling changes to be coordinated with previously scheduled changes and that manufacturers would incur costs associated with applying stickers to some sales units due to insufficient time to print new labels before the change must be implemented. Table 12 shows the total cost of a major cigarette labeling change that reflects both an effective date of six months from the date of publication of the final rule, as well as that each cigarette UPC would require 13 printing plates, one for each cigarette health warning label (13 warnings per UPC). We estimate total labeling costs associated with this proposed rule under this regulatory option range from \$695.0 million to \$3.2 billion, with a mean estimate of \$1.4 billion (2018\$).

Table 12. Cost of a Major Cigarette Label Change With 13 Warning Labels (in 2018\$)

	Low	Mean	High
Label Design Costs			
# Uncoordinated UPCs	3,063	3,063	3,063
Labor Costs (\$/UPC)	\$4,495	\$9,603	\$18,069
Material Costs (\$/UPC)	\$97,138	\$122,861	\$152,068
Recordkeeping Costs (\$/UPC)	\$49	\$94	\$163
Total Costs (\$/UPC)	\$101,682	\$132,558	\$170,300
Total Label Design Costs for Uncoordinated UPCs (\$)	\$311,451,966	\$406,025,154	\$521,628,900
# Coordinated UPCs	0	0	0
Labor Costs (\$/UPC)	\$395	\$1,354	\$3,059
Material Costs (\$/UPC)	\$89,666	\$113,410	\$140,370
Recordkeeping Costs (\$/UPC)	\$17	\$34	\$60
Total Costs (\$/UPC)	\$90,078	\$114,798	\$143,489
Total Label Design Costs for Coordinated UPCs (\$)	\$0	\$0	\$0
TOTAL LABEL DESIGN COSTS (\$)	\$311,451,966	\$406,025,154	\$521,628,900
Inventory Costs			
# Discarded Labels	15,440,782	15,440,782	15,440,782
Cost Per Discarded Label (\$/Label)	\$0.027	\$0.032	\$0.037
Total Discarded Inventory Cost	\$416,901	\$494,105	\$571,309
# Units to Which Stickers Would Be Applied	4,911,789,429	4,911,789,429	4,911,789,429
Sticker and Application Cost (\$/Unit)	\$0.078	\$0.201	\$0.551
Total Sticker Cost	\$383,119,576	\$987,269,675	\$2,706,395,975
TOTAL INVENTORY COSTS (\$)	\$383,536,477	\$987,763,780	\$2,706,967,284
TOTAL COSTS	\$694,988,443	\$1,393,788,934	\$3,228,596,184

Notes: FDA's own analyses and calculations are based in part on data reported by Nielsen through its RMS service for the cigarettes category for the 52-week period ending December 29, 2018 for the total United States market and Convenience Stores and Expanded All Outlets Combined (xAOC) channels. Copyright © 2018, The Nielsen Company. The conclusions drawn from the Nielsen data are those of the FDA and do not reflect the views of Nielsen. Nielsen is not responsible for and had no role in and was not involved in analyzing and preparing the results reported herein. Nielsen RMS data consist of weekly purchase and pricing data generated from participating retail store point-of-sale systems in all U.S. markets. See <http://www.nielsen.com/us/en.html> for more information. Effective date is six months from the date of publication of the final rule. We used 2018 Nielsen RMS data to estimate the number of cigarette UPCs. The number of uncoordinated and coordinated UPCs depend on the number of cigarette UPCs as well as, respectively, the percentage of UPCs which cannot and can be coordinated, both of which are estimated using the FDA Labeling Cost Model. The number of discarded labels depends on the estimated number of sales units, the source of which is 2018 Nielsen RMS data, as well as an estimate of the percentage of those sales units which will be discarded, the latter which is estimated using the FDA Labeling Cost Model. The number of units to which stickers would be applied depends on the estimated number of sales units, the source of which is 2018 Nielsen RMS data, as well as an estimate of the percentage of those sales units which would be stickered, the latter which is estimated using the FDA Labeling Cost Model. Lastly, note that Nielsen only provides a point estimate of UPCs and sales units, not a range. Hence, the number of UPCs and the number of discarded labels is the same at low, mean, and high.

The total cost of the proposed rule if the effective date is six months from the date of publication of the final rule is presented in Table 13. Under such an effective date, the present value of the estimated total costs of the proposed rule ranges from \$1.7 billion to \$4.6 billion, with a mean estimate of \$2.6 billion, using a three percent discount rate, and ranges from \$1.4 billion to \$4.0 billion, with a mean estimate of \$2.1 billion, using a seven percent discount rate (2018\$). The estimated annualized cost of the proposed rule ranges from \$113.8 million to \$306.8 million, with a mean estimate of \$172.2 million, using a three percent discount rate, and ranges from \$128.7 million to \$379.1 million, with a mean estimate of \$202.8 million, using a seven percent discount rate (2018\$).

Table 13. Estimated Total Cost of the Proposed Rule if the Effective Date is Six Months from the Date of Publication of the Final Rule (in millions of 2018\$)

	Non-Discounted		
t	Low	Mean	High
1	\$719.1	\$1,418.3	\$3,253.5
2	\$24.1	\$24.5	\$24.9
3	\$24.1	\$24.5	\$24.9
4	\$206.0	\$257.0	\$316.6
5	\$24.1	\$24.5	\$24.9
6	\$24.1	\$24.5	\$24.9
7	\$191.7	\$238.7	\$293.7
8	\$24.1	\$24.5	\$24.9
9	\$24.1	\$24.5	\$24.9
10	\$178.5	\$221.9	\$272.6
11	\$24.1	\$24.5	\$24.9
12	\$24.1	\$24.5	\$24.9
13	\$166.4	\$206.3	\$253.0
14	\$24.1	\$24.5	\$24.9
15	\$24.1	\$24.5	\$24.9
16	\$155.1	\$192.0	\$235.1
17	\$24.1	\$24.5	\$24.9
18	\$24.1	\$24.5	\$24.9
19	\$144.8	\$178.8	\$218.5
20	\$24.1	\$24.5	\$24.9
Present Value			
3%	\$1,693.5	\$2,561.5	\$4,563.8
7%	\$1,363.3	\$2,148.1	\$4,016.4
Annualized Amount			
3%	\$113.8	\$172.2	\$306.8
7%	\$128.7	\$202.8	\$379.1

Notes: Effective date is six months from date of publication of final rule. Included in $t = 1$ is the initial cost associated with changing cigarette labels, illustrated in Table 4. Included in $t = 4, 7, 10, 13, 16$, and 19 are costs associated with planned future cigarette labeling changes from Table 5. Included in $t = 1$ through $t = 20$ are annual design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements from Table 6, advertising opportunity costs illustrated in Section 4, and government administration and enforcement costs illustrated in Section 5.

If the information provided by the cigarette health warning on each package were valued at about \$0.02 (for every pack sold annually nationwide), then the benefits generated by the proposed rule with an effective date of six months from the date of

publication of the final rule would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018\$).

3. Nine Cigarette Health Warnings

An otherwise identical rule requiring that one of up to nine new cigarette health warnings appear on cigarette packages and in cigarette advertisements would reduce both the initial and recurring labeling costs of this rule through a reduction in material costs. Table 14 shows the total cost of a major cigarette labeling change that reflects both an effective date of 15 months from the date of publication of the final rule, as well as that each cigarette UPC would require nine printing plates, one for each cigarette health warning label (nine warnings per UPC). We estimate total initial labeling costs associated with this proposed rule under this regulatory option range from \$217.4 million to \$372.2 million, with a mean estimate of \$286.3 million (2018\$).

Table 14. Cost of a Major Cigarette Label Change With 9 Warning Labels (in 2018\$)

	Low	Mean	High
<u>Label Design Costs</u>			
# Uncoordinated UPCs	2,819	2,819	2,819
Labor Costs (\$/UPC)	\$4,495	\$9,603	\$18,069
Material Costs (\$/UPC)	\$67,248	\$85,059	\$105,282
Recordkeeping Costs (\$/UPC)	\$49	\$94	\$163
Total Costs (\$/UPC)	\$71,792	\$94,756	\$123,514
Total Label Design Costs for Uncoordinated UPCs (\$)	\$202,381,648	\$267,117,164	\$348,185,966
# Coordinated UPCs	244	244	244
Labor Costs (\$/UPC)	\$395	\$1,354	\$3,059
Material Costs (\$/UPC)	\$59,776	\$75,608	\$93,584
Recordkeeping Costs (\$/UPC)	\$17	\$34	\$60
Total Costs (\$/UPC)	\$60,188	\$76,996	\$96,703
Total Label Design Costs for Coordinated UPCs (\$)	\$14,685,872	\$18,787,024	\$23,595,532
TOTAL LABEL DESIGN COSTS (\$)	\$217,067,520	\$285,904,188	\$371,781,498
<u>Inventory Costs</u>			
# Discarded Labels	11,611,468	11,611,468	11,611,468
Cost Per Discarded Label (\$/Label)	\$0.027	\$0.032	\$0.037
TOTAL INVENTORY COSTS (\$)	\$313,510	\$371,567	\$429,624
TOTAL COSTS	\$217,381,030	\$286,275,755	\$372,211,122

Notes: Effective date is 15 months from date of publication of final rule.

Regarding labeling costs related to planned future labeling changes, per-UPC recurring labeling costs range from \$43,109/UPC to \$69,965/UPC with a mean estimate of \$55,394/UPC (2018\$). Total labeling costs in years 1 (reproduced from above), 4, 7, 10, 13, 16, and 19 are illustrated below in Table 15.

Table 15 - Cost of Planned Future Major Cigarette Label Changes With 9 Warning Labels (in 2018\$)

t	# UPCs	Labeling Costs		
		Low	Mean	High
1	3,063	\$217,381,030	\$286,275,755	\$372,211,122
2	2,980	-	-	-
3	2,900	-	-	-
4	2,822	\$121,653,598	\$156,321,868	\$197,441,230
5	2,746	-	-	-
6	2,672	-	-	-
7	2,600	\$112,083,400	\$144,024,400	\$181,909,000
8	2,530	-	-	-
9	2,462	-	-	-
10	2,396	\$103,289,164	\$132,724,024	\$167,636,140
11	2,331	-	-	-
12	2,268	-	-	-
13	2,207	\$95,141,563	\$122,254,558	\$154,412,755
14	2,147	-	-	-
15	2,089	-	-	-
16	2,033	\$87,640,597	\$112,616,002	\$142,238,845
17	1,978	-	-	-
18	1,925	-	-	-
19	1,873	\$80,743,157	\$103,752,962	\$131,044,445
20	1,822	-	-	-

Notes: Effective date is 15 months from date of publication of final rule.

The total cost of the proposed rule if the effective date is 15 months from the date of publication of the final rule and the number of cigarette health warnings is nine is presented in Table 16. Under such a scenario, the present value of the estimated total costs of the proposed rule ranges from \$1.0 billion to \$1.4 billion, with a mean estimate of \$1.2 billion, using a three percent discount rate, and ranges from \$765.1 million to \$1.1 billion, with a mean estimate of \$921.1 million, using a seven percent discount rate (2018\$). The estimated annualized cost of the proposed rule ranges from \$68.0 million to \$97.3 million, with a mean estimate of \$81.3 million, using a three percent discount rate, and ranges from \$72.2 million to \$104.7 million, with a mean estimate of \$86.9 million, using a seven percent discount rate (2018\$).

Table 16. Estimated Total Cost of the Proposed Rule (in millions of 2018\$)

	Non-Discounted		
t	Low	Mean	High
1	\$241.5	\$310.8	\$397.1
2	\$24.1	\$24.5	\$24.9
3	\$24.1	\$24.5	\$24.9
4	\$145.8	\$180.8	\$222.3
5	\$24.1	\$24.5	\$24.9
6	\$24.1	\$24.5	\$24.9
7	\$136.2	\$168.5	\$206.8
8	\$24.1	\$24.5	\$24.9
9	\$24.1	\$24.5	\$24.9
10	\$127.4	\$157.2	\$192.5
11	\$24.1	\$24.5	\$24.9
12	\$24.1	\$24.5	\$24.9
13	\$119.2	\$146.8	\$179.3
14	\$24.1	\$24.5	\$24.9
15	\$24.1	\$24.5	\$24.9
16	\$111.7	\$137.1	\$167.1
17	\$24.1	\$24.5	\$24.9
18	\$24.1	\$24.5	\$24.9
19	\$104.8	\$128.3	\$155.9
20	\$24.1	\$24.5	\$24.9
Present Value			
3%	\$1,011.1	\$1,209.8	\$1,448.3
7%	\$765.1	\$921.1	\$1,109.2
Annualized Amount			
3%	\$68.0	\$81.3	\$97.3
7%	\$72.2	\$86.9	\$104.7

Notes: Effective date is 15 months from date of publication of final rule. Included in $t = 1$ is the initial cost associated with changing cigarette labels, illustrated in Table 14. Included in $t = [4, 7, 10, 13, 16, 19]$ are costs associated with planned future cigarette labeling changes from Table 15. Included in $t = 1$ through $t = 20$ are annual design and operation costs associated with the random and equal display and distribution and quarterly rotation requirements from Table 6, advertising opportunity costs illustrated in Section 4, and government administration and enforcement costs illustrated in Section 5.

If the information provided by the cigarette health warning on each package were valued at about \$0.009 (for every pack sold annually nationwide), then the benefits generated by the proposed rule under this regulatory option would equal or exceed the estimated annualized costs at three and seven percent discount rates (2018\$).

available, annual receipts per tobacco manufacturer employing less than 500 employees range from about \$4.5 million per firm (those with less than 20 employees) to roughly \$102 million per firm (those with 100 to 499 employees) (2018\$),²² and annual receipts per tobacco wholesaler employing less than 100 employees range from about \$7.9 million per firm (those with less than 20 employees) to roughly \$65.2 million per firm (those with 20 to 99 employees) (2018\$).²³ Thus, we estimate that initial costs for a small cigarette manufacturer or importer would represent between 2.5 percent (= \$2.6 million / \$102 million) and 35.6 percent (= \$1.6 million / \$4.5 million) of their annual receipts, and recurring costs would represent between 0.4 percent (= \$0.4 million / \$102 million) and 4.4 percent (= \$0.2 million / \$4.5 million) of their annual receipts.

2. Alternatives to Minimize the Burden on Small Entities

The biggest source of the burden of this rule on small entities is the initial cost associated with changing cigarette labels. One way in which this burden could be eased is to extend the effective date for small manufacturers and importers. For example, if the effective date was increased to 24 months from the date of publication of the final rule for small manufacturers and importers, then for a small manufacturer or importer affected by the proposed rule, we estimate that initial labeling costs would represent between 1.8 percent and 24.4 percent of their annual receipts, compared to between 2.5 percent and 35.6 percent of annual receipts if the effective date was 15 months from the date of

²² See “Data by Enterprise Employment Size, U.S. and States, U.S., 6-digit NAICS” at <https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html>. The most granular that we could get using these data is NAICS 312230, “Tobacco Manufacturing”, versus our desired granularity of NAICS 312221, “Cigarette Manufacturing”.

²³ See “Data by Enterprise Employment Size, U.S. and States, U.S., 6-digit NAICS” at <https://www.census.gov/data/tables/2012/econ/susb/2012-susb-annual.html>. We used NAICS 424940.

publication of the final rule (note that the recurring costs do not vary by effective date and so would not change). An even further out effective date would reduce initial labeling costs even more. One possible downside to extending the effective date for small manufacturers and importers, however, is that doing so could result in different cigarette products bearing different warnings, thus potentially creating consumer confusion about the relative risk of those different cigarette products.